UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,261	04/04/2002	Jacques Bartholeyns	USB 99 AL IDM TARG	8153

466 7590 05/03/2005

YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,261	BARTHOLEYNS ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-8, filed 2/11/05, is acknowledged. Applicant argues that the lack of a special technical feature has not been shown. Specifically, Applicant argues that Fiani et al. does not teach the cell of the instant claims.

Applicant has argued that, "FIANI et al. merely disclose macrophage cells which have taken up and processed antigens via interaction between glycoproteins and glycoprotein-binding receptors." It is the Examiner's position that this cell meets the limitations of the claims. The method of loading macrophages or dendritic cells of Claims 1-8 merely comprises an assertedly more efficient way of getting antigens into an antigen presenting cell (through a scavenger receptor). Accordingly, regardless of the nomenclature employed by Applicant (e.g., molecular complex, molecular vector, etc.), the cell of Claim 9 merely comprises a macrophage or dendritic cell loaded with antigen, i.e., the cell of Fiani et al.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-16 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-8 are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, it is unclear how a complex can be formed between an entire tissue extract and a particle. A tissue extract would most likely be a liquid composition comprising soluble and non-soluble components. While a particle might be able to form a complex with a

particular component of a tissue extract, it is unlikely, and seemingly impossible, that a complex could be formed with an entire extract. Accordingly, the metes and bounds of the claimed invention are unclear.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the claimed "molecular complex".

The "molecular complex" of the of the instant claims comprises (among other things) any known cellular proteins or sugars, any unknown proteins and sugars, and a carrier "of molecular structure", i.e., anything that binds the known component to a ligand of a phagocytic receptor of a monocyte derived cell. Clearly, the genus of "molecular complexes" encompassed by the claims is essentially unlimited. An adequate written description of the claimed invention would comprise at least a disclosure of a representative number of species of the claimed complexes. A review of the specification, however, discloses no actual "molecular complexes" meeting the limitations of the instant claims. A few of the "known components" of the claimed complexes are disclosed at page 4 of the specification. All of said "known components" are tumor (or more properly, tumor associated) antigens. Clearly this minimal

disclosure is not representative of all of the "known components" encompassed by the claims. No species of the "unknown components" of the complex are disclosed, although, again at page 4 of the specification it is discloses that the tissue extracts of the claims contain "normal tissue parts such as tissue membranes, tissue factors, tissue proteins, macroscopic fragments of tissue such as lysates or apoptopic bodies, said tissue being originating from any part of human or animal body or cellular extracts thereof," which would likely be the source of the "unknown components" of the complex. Again, this minimal disclosure, is not representative of all of the "unknown components" of the complex of the claims. Additionally, none of the ligands of "phagocytic receptors of a monocyte derived cell" encompassed by the claims are disclosed. Thus, of the three components of the "molecular complex" of the claims, a non-representative number of species of one component is disclosed, and no species of the other two of the components are disclosed.

Regarding the examples, where one might expect to find examples of the claimed invention, neither example discloses a "molecular complex" meeting the limitations of the claims. Example 1 discloses a microparticle, to which annexin V polypeptides are linked, added to a solution of apoptotic bodies. There is no indication of any complex being formed, no disclosure of a "known component" being bound by the particle, nor any disclosure of a ligand of a "phagocytic receptor of a monocyte derived cell". Example 2 discloses that microparticles presenting mannosyl residues at their surfaces are added to a suspension of killed murine hepatocytes and "molecular complexes" are formed. These are clearly not the "molecular complexes" of the instant claims because killed murine hepatocytes are not tissue extracts. Thus, the Example discloses no tissue extract, no bound "unknown component", and no ligand of a "phagocytic receptor of a monocyte derived cell".

Clearly then, one of skill in the art would conclude that the specification fails to disclose a representative number of species to adequately describe the "molecular complexes" of the instant claims. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence that any "molecular complexes" of the instant claims can be made.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity (and, thus, products made from and intended for use with physiologic sources) can be considered inherently unpredictable.

Regarding the "molecular complexes" of the instant claims, it is noted (as set forth above) that the complexes are inadequately and unclearly described. It is conceivable, however, that the skilled artisan could make an invention that was inadequately described; but it would be scientifically appropriate then to conclude that significant guidance would be required. A review of the specification discloses that no guidance of any type is given regarding the making of the claimed "molecular complexes". Indeed, the specification merely states repeatedly that the invention "relates" to various methods. At best, then the skilled artisan is left with

guessing how to make the claimed invention, and then employing methods of trial-and-error. As methods of trial-and-error provides no particular expectation of success that any particular complexes produced would meet the limitations of the claims, said methods are considered to be unpredictable, thus, necessitating undue experimentation.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/21/05

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600